

Application No.: 10/033,571

Docket No.: 29853/37702

REMARKS**I. Preliminary Comments**

Applicants wish to thank the Examiner for the courtesy shown to the undersigned attorney during the telephonic interview conducted October 6, 2005. Applicants discussed the preceding amendments addressing the Section 112 rejection as well as distinctions between the claims as amended and the cited art.

Applicants note with gratitude that the Examiner has withdrawn the previous rejections under 35 U.S.C. § 112 (first paragraph) and for obviousness-type double patenting and has further withdrawn certain of the rejections under 35 U.S.C. § 112 (second paragraph) relating to recitation of steps. Applicants further note that claims 71, 74 and 98 are indicated to be free of the prior art.

Applicants hereby amend independent claim 70, from which all claims depend, to incorporate the limitation of claim 73 (an adenovirus composition characterized by having "a contaminating nucleic acid concentration of less than 0.8 ng/ml"). Claim 73 is hereby cancelled. Applicants also amend claim 70 to delete the reference to "for therapeutic use" and clarify that the method provides a "pharmaceutically acceptable." Finally, claims 71, 72, 74-78, 82, 88-90 and 94-98 are amended consistent with the amendment to claim 70 to delete the recitation of "for therapeutic use." These amendments place the claims in condition for allowance and do not introduce new matter into the application.

II. Outstanding Rejections

Claims 70-98 remain rejected under 35 U.S.C. § 112 (second paragraph) as being indefinite for reciting "suitable for therapeutic use."

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Claims 70, 72-73, 75-77 and 80-97 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Shabram et al., U.S. Patent 5,837,520 (having a U.S. filing date of March 7, 1995 compared to the application's priority date of November 20, 1996) in view of Perrin et al., (Vaccine 13(13):1244-1250, 1995), Garnier et al., (Cytotechnology 15:145-155, 1994), and/or Nadeau et al., (Biotechnology and Bioengineering 51:613-623, 1996).

Dependent claims 78 and 79 directed to serum-free compositions and media also remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Shabram in view of Perrin, Garnier and/or Nadeau and further in view of Morris et al., (Williamsburg BioProcessing Conference, Nov. 18-21, 1996) or Gilbert (Williamsburg BioProcessing Conference, Nov. 18-21, 1996).

III. Patentability Arguments

The claims as amended above should be allowed in light of the foregoing amendments and for the reasons set out below.

A. The Indefiniteness Rejection of Claims 70-98 Under 35 U.S.C. §112 (second paragraph) Should be Withdrawn.

The indefiniteness rejection should be withdrawn in light of the amendment of the claims to delete the recitation of "suitable for therapeutic use." Applicants disagree with the Examiner's rejection as the original claim language was directed to the intended use of the composition and would not operate as a limitation. Nevertheless, Applicants hereby amend the recitation of their claims to a more conventional format wherein the composition is recited as being "pharmaceutically acceptable." This language is conventional in the art and is supported in the specification such as at page 72, line 11 through page 75, line 18.

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**B. The Rejection of Claims 70, 72, 75-77 and 80-97 Under
35 U.S.C. §103(a) Over Shabram et al. US 5,837,520
In View of Perrin, Garnier and/or Nadeau Should be Withdrawn.**

The rejection of claims 70, 72, 75-77 and 80-97 under 35 U.S.C. §103(a) over Shabram et al. US 5,837,520 in view of Perrin, Garnier and/or Nadeau should be withdrawn in light of the amendment of independent claim 70 to incorporate the limitation of claim 73 reciting that the purified composition has a contaminating nucleic acid concentration of less than 0.8 ng/ml. Applicants note that claim 74 which recites a contaminating nucleic acid concentration of less than 0.2 ng/ml was previously found to be free of the art and submit that the art also fails to disclose or suggest purified compositions having a contaminating nucleic acid concentration of less than 0.8 ng/ml.

While Applicants maintain that the cited references fail to teach the method recited by original claim 70 (prior to the foregoing amendment) they further submit that the cited references fail to make out a prima facie case of obviousness of claim 70 as now amended to recite a contaminating nucleic acid concentration of less than 0.8 ng/ml. Specifically, there is nothing in any of Shabram, Perrin, Garnier or Nadeau that teaches the reduction of contaminating nucleic acid levels to the levels now claimed or suggests that the methods of the claims would achieve those levels. For example, Perrin relates to culturing of rabies virus and as such is irrelevant to the issue of culturing and purifying adenovirus products. Garnier and Nadeau relate to purification methods but there is nothing in those references which would lead one to expect that Applicants' methods would produce adenovirus materials of the purity recited. In the absence of some suggestion in the references that Applicants' method would achieve contaminating nucleic acid concentrations of less than 0.8 ng/ml the rejection under the combination of those references should be withdrawn.

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**C. The Rejection of Claims 78 and 79 Under 35 U.S.C. §103(a)
Over Shabram, In View Of Perrin, Garnier and/or Nadeau and
Further In View of Morris or Gilbert Should be Withdrawn.**

The rejection of 78 and 79 depending from claim 70 should also be withdrawn in light of the amendment of claim 70 from which those claims depend to incorporate the limitation of claim 73.

While Morris and Gilbert might disclose the production of adenovirus in cells adapted to serum-free media they do not suggest that doing so according to the practice of Applicants' invention would yield a product with improved purity having a contaminating nucleic acid level of less than 0.8 ng/ml as currently claimed by Applicants.

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CONCLUSION

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Respectfully submitted,

MARSHALL, GERSTEIN & BORUN LLP
6300 Sears Tower
233 South Wacker Drive
Chicago, Illinois 60606
312-474-6300

By: 

Jeffrey S. Sharp
Registration No. 31,879
Attorney for Applicants

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